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Equipment Alternatives: History and Prospects

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Introduction

During the past four or five years, a good deal of attention has been focused on early intervention in cases of amenorrhea using small, inexpensive vacuum sources and soft plastic cannulae. Terminology developed early in such research varied, but settled for the main part on the term *menstrual regulation*. This was defined as a vacuum aspiration procedure performed within two weeks of a missed period.

Two significant results have come from extensive international study,[3] and these have implications for both equipment makers and users involved in providing health care to women. These are as follows:

1. Interception in the first week following a missed period was accompanied by a higher rate of procedural failures and a significant number of patients were nonpregnant.
2. The capabilities of the small vacuum source and soft cannulae appeared to be adequate for management of gestations approaching eight weeks LMP (since the last menstrual period).

The combined effect of these findings is reflected in the Pathfinder Fund's definition of a procedure called *menstrual induction*, which includes vacuum aspiration procedures performed at 35 to 55 days from the missed period. This definition recognizes the problem of too early intervention and the capacity of the basic technique to deal with cases beyond six weeks LMP.

The term "menstrual induction" more accurately reflects the world trend in service than does the more limited "menstrual regulation" definition used in initial research. The principal problem with this trend toward treatment later in the first trimester is that the limitations of some types of equipment are being approached, even with accurate

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diagnosis of gestation. As noted by King, et al in a recent review paper,[6] underestimation of gestation is a common problem.

The implications for the design of equipment are rather clear, and break into two parts. First, there is the expressed desire of many clinicians for a hand-held instrument of somewhat higher capacity than the well-known 50 cc syringe aspirator. Second, there is a need for a significantly higher capacity instrument for use as a backup system in cases of gross underestimation of gestation (as well as for treatment of septic or incomplete abortions).

This paper briefly reviews the principal developments in vacuum instruments for menstrual induction and first-trimester vacuum termination of pregnancy. It will focus mainly on nonelectrical vacuum sources developed by Battelle Laboratories, but will also touch on the history of this equipment's development.

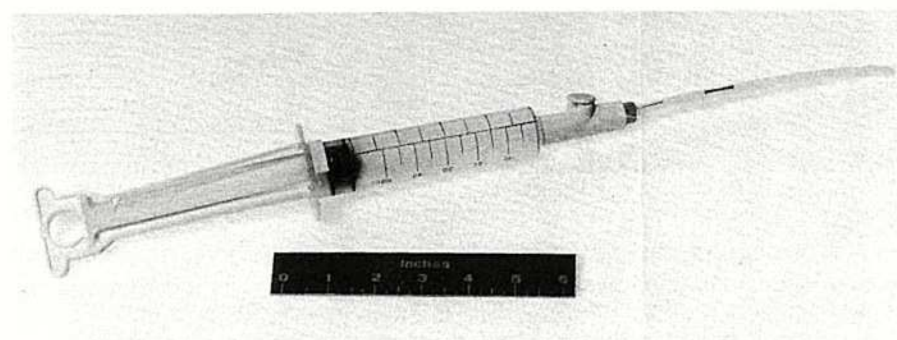
Vacuum Sources

Vacuum sources used in menstrual induction and other first trimester aspiration procedures fall into three categories: syringe aspirators of limited volume and vacuum capacity; negative pressure bottles of somewhat larger volume and vacuum capacity; and collection bottles with attached pumps.

Syringe Aspirators

Although the use of syringes for treatment of amenorrhea or early pregnancy termination was reported as early as 1872 by Simpson[11] and 1927 by Bykov,[2] the modern use of the instrument for these purposes is mainly traceable to work in China by Liu in 1966[8] and in the West by Karman and Potts in 1972.[5] The original Karman design, in conjunction with soft plastic cannulae, started a wide scale international study of early aspiration procedures. It has a capacity of 50 ml.

Figure 1. Syringe Aspirator, Battelle Design

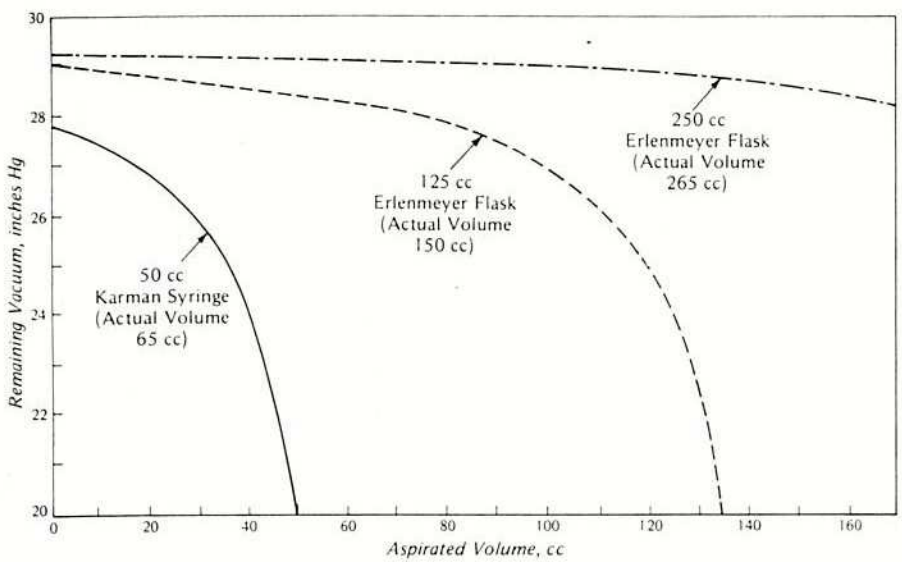


The original Karman design was improved in some important ways by the Battelle group. Modifications included an improved locking handle and a vacuum control valve so that the instrument can be evacuated without connection to the uterus. This provides advantages both in manipulative ease and in safety. The instrument is shown in Figure 1, and has been previously described by Williford and Wheeler (1975).[13] Since late in 1973, this particular instrument has become an international standard for menstrual regulation research. It is made and supplied by the International Pregnancy Advisory Services organization in the U.S. and by Chimco in Bombay, India.

Negative Pressure Bottles

One drawback of the syringe aspirator is its limited capacity. The problem with volume limitations is illustrated in Figure 2, which plots remaining vacuum as a function of the amount of material aspirated for three static vacuum systems of increasing volume. These plots are calculated values, and reflect the best of circumstances.

Figure 2. Remaining Vacuum Versus Aspirate Volume for Three Static Negative Pressure Systems

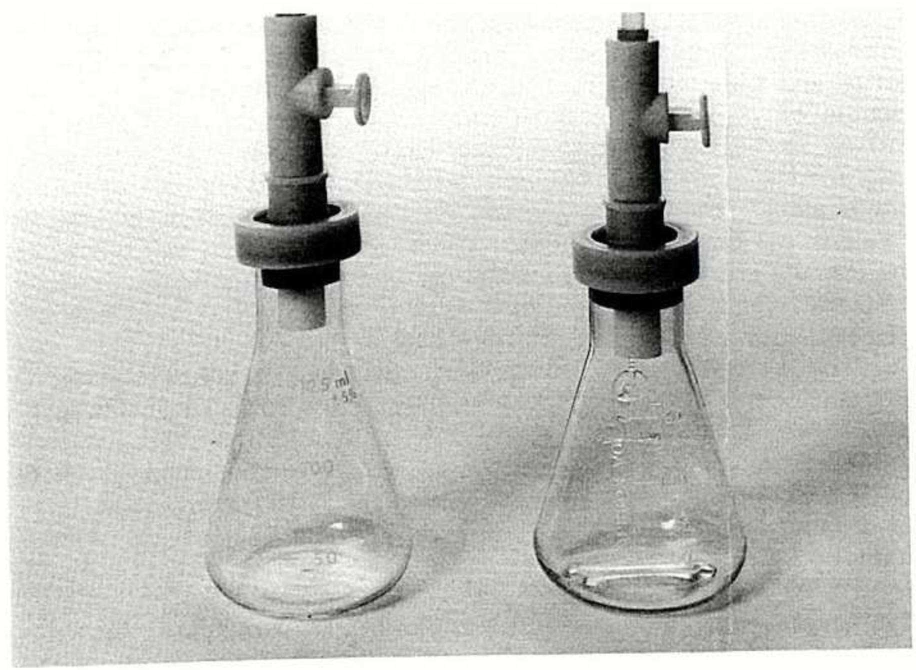


Considering the increasing amounts of amniotic fluid, blood and tissue with advancing gestation, it is clear that a syringe evacuated one-time has limited use in the first trimester.

Since there are very great physical forces involved in moving a piston larger than the plunger of the syringe, it is not possible to conveniently increase the volume of a syringe-type aspirator. A number of investigators have used containers evacuated by a variety of methods to obtain increased capacity while maintaining simplicity. The mainland Chinese have been using instruments for over 10 years called "negative pressure bottles." Favorable results are reported by P'an[10] and by Wu and Shang.[15] Use of this approach in the U.S. was reported by Branch and Bridgeman (1973).[1] A disposable, pre-evacuated bottle has just appeared on the U.S. market made by Warner-Chilcott.

Battelle's involvement with the negative pressure bottle followed the early findings with the modified Karman syringe. The current model of our reusable instrument is shown in Figure 3. Two versions of the bottle are in trial at present. One uses a glass flask and is evacuated by boiling water, a time-honored method of creating a good vacuum which I will discuss later. The other uses a lightweight and unbreakable plastic flask, and is evacuated with a mechanical pump or with a water aspirator. Both versions use 125 ml graduated erlenmeyer flasks.

Figure 3. Battelle Negative Pressure Bottles



The current version of the Battelle negative pressure bottle uses the same pinch valve as that on the modified Karman syringe. Clinical results to date indicate that the instrument is readily usable to between 8 and 9 weeks LMP, and that the cannula size limitation imposed by the valve design appears to be more of a factor in dealing with more advanced gestations than gross capacity.[10] A new valve is being readied for trial.

Collection Containers with Attached Mechanical Pumps

In dealing with the aspirate volumes encountered in late first trimester or early second trimester abortion, advantages of a large collection container become important. An attached pump is useful when it is necessary to re-establish a vacuum that was lost by clearing the cannula or inadvertently withdrawing it from the cervix.

Manually pumped aspirators of various types have been shown to be effective in managing termination of first trimester pregnancy.[4,7] Examples include the Rocket of London and Warden Surgical Company hand-powered aspirators—modified bicycle-pump designs that depend on manually closing valves to prevent leakage through the pump in use. Foot-operated pumps include the Berkeley Pedipump which is pumped with the toe, and the India-made Poona pump in Figure 4, which is pumped with less effort using the heel of the foot.

In our own work, we have centered on a completely new design that works solely as a vacuum pump, and cannot be modified to produce pressure. The pump is shown in Figure 5, attached to a 500 ml collection bottle and base. The pump works on the downward stroke, and a vacuum of 25 inches (63.5 cm) of mercury is produced in about 18 strokes. The leakage of this system is almost nil, and it can be prepared well in advance of need. Vacuum is controlled by the operator with a simple pinch valve near the cannula. This valve, shown in more detail in Figure 6, can be closed during the procedure to conserve vacuum when the cannula is withdrawn from the cervix for clearing or for checking completion of tissue removal with a blunt curette. This system is described in more detail in Williford & Wheeler (1975).[13]

The Battelle system has been used without difficulty in terminating pregnancies up to 12 weeks LMP, using cannulae up to 10 mm in diameter. However, due to the large volume of aspirate frequently encountered in these later gestations, it appears prudent to limit this instrument to 10 weeks LMP, leaving some margin for diagnostic error. The Battelle hand pump is now being manufactured commercially in the United States by Burnett Instruments.

Significance and Uses of Available Vacuum Equipment

Limitations of various types of aspiration equipment have been illustrated in rather fundamental terms by showing how vacuum falls off with increasing aspirate volume (*see* Figure 2). Figure 7 lists the volume of amniotic fluid and fetal tissue at various stages of gestation.[9] Supplementary volumes must be added to account for blood loss and maternal tissues (Figure 8).

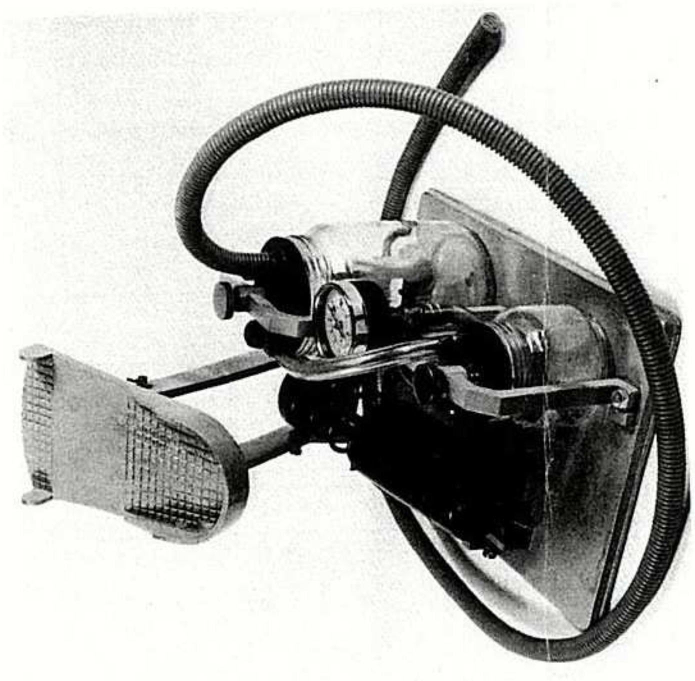


Figure 4. Poona Foot Pump, India

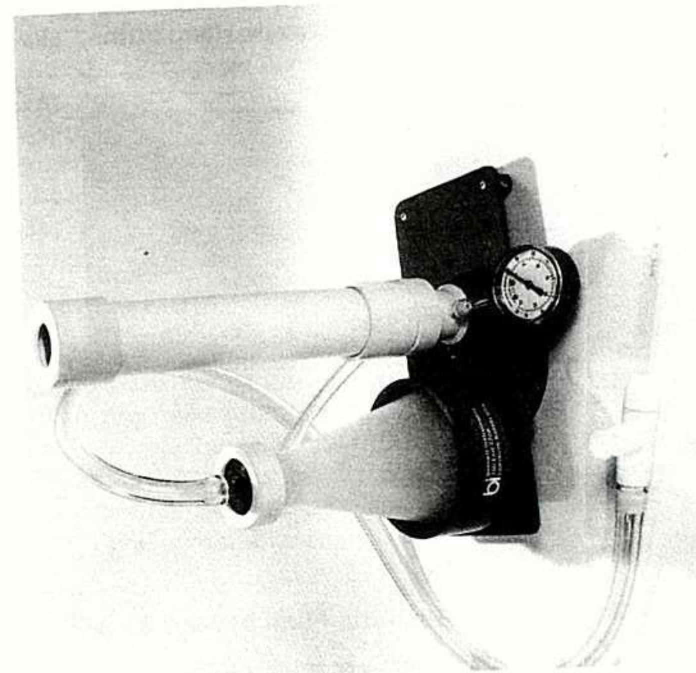


Figure 5. Battelle Hand-Pumped Uterine Aspirator

Figure 6. Pinch Valve for Battelle Hand-Pump

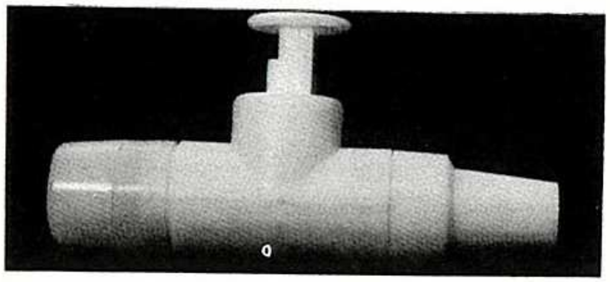


Figure 7. Volume of Amniotic Fluid by Gestation[10]

Weeks LMP	Amniotic Fluid Volume (ml)	*N*
8	14.5	*5*
10	29.6	*11*
11	45.4	*10*
12	73.9	*27*
13	89.9	*17*
14	111.3	*16*

Figure 8. Blood Losses in Vacuum Aspiration of Gravid Uterus[13] *(N = 257)*

Blood Loss Ranges (ml)	% Patients by Gestation	
	6-8 weeks	9-13 weeks
<100	91.8%	55.1%
100-200	7.3	34.7
200-300	0.9	6.1
>300	—	4.1

If the practitioner intends to deliver menstrual induction services only, either the syringe or the negative pressure bottle may reasonably be selected as primary instruments. The syringe may be re-evacuated (or a back-up syringe used) to compensate for its lower capacity. The choice of instruments in this case is largely a matter of personal preference. In either case, it is well to have a system of larger capacity at hand as a backup for misjudgement of gestation.

One combination of instruments which appears reasonable is to use the 125 ml plastic negative pressure bottle as a primary instrument. A number of these can be pumped down in advance of need with the Battelle hand-pumped aspirator. The hand-pumped system can then be readied for use if larger cannulae are necessary.

In a setting where delivery of complete first trimester services is planned, the whole range of instruments may be selected according to need. Bottles and syringes have the additional benefit of easy cleanup between procedures, and are inexpensive enough that a number of instruments can be available at one time.

Improvisation

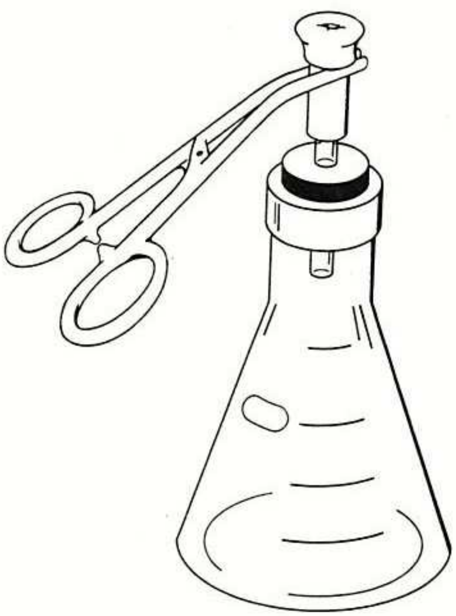
Availability of equipment is a problem in many parts of the world, but the willingness of creative clinicians to improvise is in good supply. To complete our discussion of vacuum sources, it may be helpful to point out some ways to improvise equipment. These comments are based on our own experiments, as well as work reported by others.

An Improvised Negative Pressure Bottle for Steam Evacuation

Steam evacuated negative pressure bottles are easy to improvise. Our own version of the steam evacuated bottle has a number of convenient features, such as a locking stopper, an automatic check valve to assure uniform evacuation and an easy to use pinch valve to conserve vacuum. These conveniences can, if necessary, be dispensed with, and an improvised system can be made up by anyone using the following readily available parts:

- A laboratory flask of Pyrex® or other heat-resistant glass – preferably of the erlenmeyer pattern – with a capacity of 125 to 150 ml.
- A rubber stopper to fit the flask, with a hole in it of 7 or 8 mm diameter.
- A rigid tube of metal, glass or high temperature plastic to fit the hole in the stopper, having a clear lumen at least as large as the cannula.
- A short length of latex surgical tubing, having an inside diameter (ID) of about 6 mm, and an outside diameter (OD) of about 10 mm.

Figure 9. Improvised Negative Pressure Bottle



These components, assembled, are shown in Figure 9, along with a small hemostat, which is also necessary. To use this system, put about 10 to 15 ml of water in the flask (enough to cover the bottom), insert the stopper firmly and bring the water to a vigorous boil for about a minute. Remove the flask from the heat and clamp the rubber tubing with the hemostat as close to the end of the rigid tube as possible. As soon as the flask has cooled enough to hold comfortably, a very good vacuum will have been formed by the condensation of steam to water. The vacuum created this way is limited by the vapor pressure of water, and will be about 28 inches Hg (70 cm) at body temperature. This is as high as any other system available for clinical use. The effectiveness of an improvised evacuation procedure

Figure 10. Vacuum Level as Indicated by Water Aspiration Test*

Total Aspirated Water (ml)	Vacuum (cm Hg)
50	30.5
75	45.7
100	53.3
125	68.6
140	73.7

*based on 140 ml capacity flask

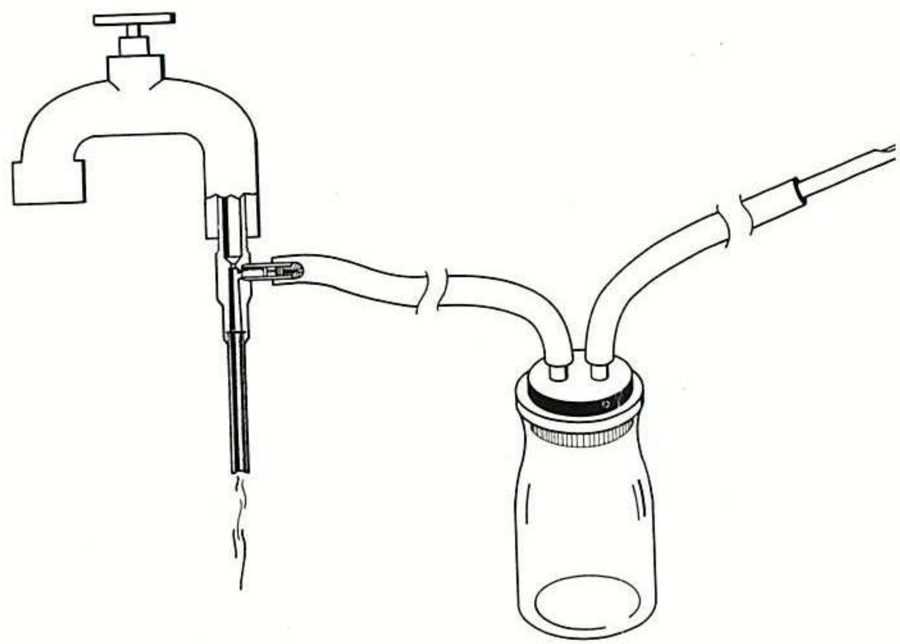
can be assessed by seeing how much water an evacuated bottle will aspirate (Figure 10).

There are some problems with such a simple system, but they can be coped with. If the tubing is clamped while the water is still boiling, the stopper is likely to be blown off. If the wait after removal from the heat is too long, air will enter the bottle and the vacuum will not be as good. Rubber tubing held with a hemostat provides a good vacuum seal, but the tube must be kept very short or it will collapse under vacuum. If the end of a 6 mm ID by 10 mm OD tube is rolled back over itself, it will hold both 5 mm and 6 mm cannulae very well. Although this can be done with a 6 mm cannula in place during the original assembly, it does take some practice. Do not attempt steam evacuation with a soft cannula in place, as it may be damaged by the heat and pressure.

Water Aspirators

Where high pressure municipal water supplies are available, simple and cheap laboratory filter pumps can be used to improvise large capacity vacuum systems. These pumps are commonly available from laboratory supply outlets for a few dollars, and may be permanently

Figure 11. Improvised Water Aspirator



attached to water faucets without harm. Vacuums as high as 28 inches Hg (70 cm) may be obtained with reasonable waterline pressures, and volumes of up to a liter may be evacuated in less than a minute at the cost of one or two gallons of water.

Wood, et al[14] have reported successful use of water aspirator vacuum sources in terminating first trimester pregnancy. Such aspirators may be used to evacuate the improvised negative pressure bottles described earlier, or may be connected to larger collection bottles by flexible plastic tubing. Such a large capacity improvised system is shown in Figure 11, in diagrammatic form. It is a good idea to put a rubber tubing and hemostat pinch valve between the water aspirator and the collection bottle so that the faucet can be shut off without loss of vacuum or ingestion of water. This valve should be closed before shutting off the water.

Vacuum Indicators

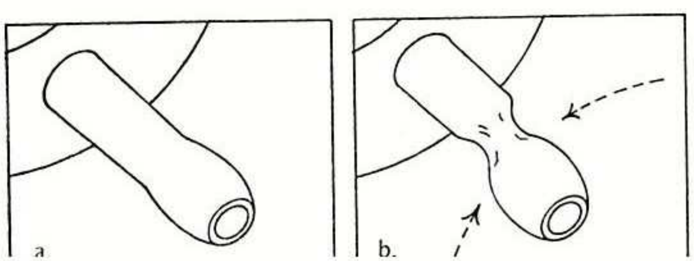
Simple and indestructible vacuum indicators can be simply improvised and used on almost any vacuum system. A simple vacuum indicator can be made by placing a length of surgical tubing, closed at one end, on a tube connected to the vacuum. The rubber tubing will collapse under vacuum along its unsupported length, and the longer the unsupported length the easier it will collapse. Using the 6 mm ID by 10 mm OD latex surgical tube as an example, an unsupported length of 15 mm collapses at about 25 inches Hg (63 cm) (Figure 12). This appears to be a reasonable operating range from reported practice. It tells the clinician essentially all he needs to know about the adequacy of the vacuum at any point in the procedure.

We have briefly described these improvised approaches to instrumentation merely to suggest some directions for those who like to explore such possibilities or are forced to do so by circumstances.

Future Prospects

Recent advances in economical equipment, along with acceptance of menstrual induction in more and more parts of the world, create a

Figure 12. Pump Vacuum Gauge: a) full vacuum, b) tube collapses as vacuum decreases



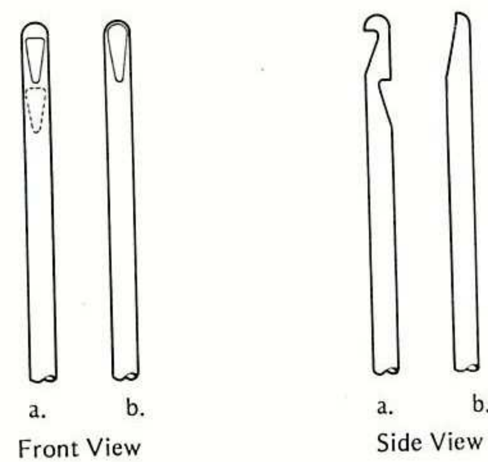
powerful trend toward provision of early pregnancy termination care to more and more women. The impact of this development, both directly as a family planning or health care measure and indirectly as a replacement for illegal or self-induced abortion, promises to be profound and global.

Looking beyond the present stage of well-developed vacuum sources and a fairly clear idea of the safety and efficacy of menstrual induction, we perceive a trend toward extension of vacuum pregnancy termination methods beyond the first trimester and into the early second trimester. In the process of continuing research on such methods, a number of clarifications or basic improvements appear likely.

First of all, current problems with cervical grasping and dilatation are receiving great attention. We expect that less traumatic tenacula designs will evolve which do not depend on penetration for fixation and will have reduced potential for laceration. We also expect to see developed alternatives to traditional dilatation. These will reduce both laceration by tenacula and tearing at the level of the inner os (particularly the lateral tears which create serious surgical problems).

In the area of cannula design and vacuum management, we expect that a trend away from the Karman pattern in larger sizes (8 mm and upwards) will accelerate, and that apertures approximating the Berkeley pattern will prevail in managing later gestations (Figure 13). A more precise definition of optimum vacuum levels for specific gestations will doubtless develop through systematic research.

Figure 13. Cannula Aperture Patterns: a) Karman; b) Berkeley



With these developments in hand, it is reasonable to expect that rates for complications through the first trimester eventually will be more closely similar for all gestational ages, and rates for early second trimester complications may reasonably be brought down to levels now reported for late first trimester procedures.

Such developments can have a great impact on the extent of first trimester service delivered worldwide; partly by reducing the requirements for the supporting medical infrastructure in the clinical setting, and partly by dealing in a positive way with the misgivings of administrators and clinicians about the danger of errors in estimating gestation.

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